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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,775	11/02/2001	Gordon Freeman	GNN-004ADV	6215
959	7590	03/29/2005	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			OUSPENSKI, ILIA I	
			ART UNIT	PAPER NUMBER
			1644	
DATE MAILED: 03/29/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/002,775

Applicant(s)

FREEMAN ET AL.

Examiner

ILIA OUSPENSKI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-16 and 25-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13-15 is/are allowed.
- 6) ☒ Claim(s) 12, 16, and 25-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment, filed 12/29/2004, is acknowledged.

Claims 1 – 11 and 17 – 24 have been cancelled previously.

Claims 12, 13, and 16 have been amended.

Claims 25 – 34 have been added.

Claims 12 – 16 and 25 – 34 are pending.

2. This Office Action will be in response to applicant's arguments, filed 12/29/2004.

The rejections of record can be found in the previous Office Action.

The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.

It is noted that New Grounds of Rejection are set forth herein.

3. Domestic priority: Applicant's amendment has obviated the previous objection of record regarding incorporation by reference of a priority application.

4. Title: Applicant's amendment has obviated the previous objection of record regarding the Title of the Invention.

5. Objections to the disclosure: Applicant's amendments have obviated the objections of record.

6. Objection to claim 16: Applicant's amendment has obviated the objection of record.

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7. Rejection of claims under **35 USC 112, second paragraph**: Applicant's amendment has obviated the rejection of record of claims 12 – 16.

Claims 16 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 16 and 25 are indefinite in the recitation of "from about amino acids 19-245 of SEQ ID NO:2 or from about amino acids 19-238 of SEQ ID NO:4," because the it is unclear whether the recitation refers to a fragment of e.g. SEQ ID NO:2 of 19 to 238 amino acids in length, or to a fragment of SEQ ID NO:2 from amino acid 19 to amino acid 238. One of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention. For examination purposes, the latter interpretation is assumed.

B. Claim 25 is indefinite in the recitation of "polypeptide consisting of from about amino acids ...," because the metes and bounds of the claimed fragment are unclear. The combination of closed language in the recitation of "consisting" with the open language of "about" crates an ambiguity, so that one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

8. Rejection of claims under **35 USC 112, first paragraph – Written Description**: Applicant's amendment to claims 13 and 16 has obviated the rejection of record of claims 13 – 16.

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Claim 12 stands rejected, and newly added claims 26 – 34 are rejected under 35 USC 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's arguments have been fully considered but were not found convincing. The rejection, as it applies to the amended and newly added claims, is maintained essentially for the reasons of record. The rejection of record is incorporated herein by reference as if reiterated in full.

Applicant argues that, according to the Eli Lilly case, a description of a genus may be achieved by a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. Applicant further argues that, according to the Interim Guidelines for Examination of Patent Applications Under 35 USC 112, First Paragraph, Written Description Requirement, if the sequence which defines and limits the structure of any effective molecules such that one skilled in the art would be able to immediately envisage members of the genus embraced by the claim, the claimed invention is adequately described.

This is not found persuasive.

First, it is noted that the test for adequate written description under 35 USC 112, first paragraph, is whether or not Applicant was in possession of the claimed invention at the time the invention was made.

With regard to claim 12, as presently amended, Applicant has not provided adequate written description of structural features common to fragments of at least 15 amino acids of SEQ ID NO:2 or 4, nor provided a sequence which defines and limits the

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structure of any such fragments, therefore, the claimed invention is not adequately described.

With regard to claim 26, and claims dependent thereon, it is noted that the hybridization conditions recited in the claim (e.g. washing at 50°C) are only moderately stringent, and therefore allow a high degree of sequence variation. Furthermore, in the absence of a recitation that requires hybridization to occur over the full length of the respective molecules, the claim language encompasses fragments of the sequence. As set forth supra in the discussion of claim 12, Applicant has not provided adequate written description of structural features common to fragments of SEQ ID NO:2 or 4, nor provided a sequence which defines and limits the structure of any such fragments such that one skilled in the art would be able to immediately envisage members of the genus embraced by the claim.

With regard to claims 29 and 32, and claims dependent thereon, the recitation of 90% identity language is not seen as providing adequate written description of structural features common to the claimed sequences, nor is it seen as defining or limiting the structure of any such sequences such that one skilled in the art would be able to immediately envisage members of the genus embraced by the claim.

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, §1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3).

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Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended and newly added claims.

9. Rejection of claims 12 – 16 under **35 USC 112, first paragraph –**

Enablement: Applicant's amendment to claims 13 and 16 has obviated the rejection of record of claims 13 – 16.

Claim 12 stands rejected, and newly added claims 26 – 34 are rejected under 35 USC 112, first paragraph, because the specification, while being enabling for isolated polypeptides of SEQ ID NO:2 or 4, or encoded by nucleic acids of SEQ ID NO:1 or 3, does not reasonably provide enablement for polypeptides comprising fragments of, or encoded by nucleic acids which hybridize to, or are at least about 90% identical to the recited sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant argues that the specification provides guidance to one of skill in the art in that it discloses that B7-4 family of molecules share a number of conserved regions, such as including signal domains, IgV domains and IgC domains. Applicant cites a review by Rost (Appendix A) as evidence that secondary structure prediction was considered to reach a relatively high level of accuracy by 2001.

This is not found persuasive.

First, it is noted that the test for enablement under 35 USC 112, first paragraph, is whether a person of skill in the art is enabled to make and use the claimed invention.

With regard to Applicant's argument that B7-4 molecules share conserved regions, it is noted that the claim language does not require that any conserved domains be present in the claimed molecules. Furthermore, based on only two disclosed sequences, it would take undue experimentation on the part of a skilled artisan to determine which of the numerous possible variants possess the functional properties of B7-4 molecules.

With regard to the Rost reference, it is noted it is the functional activity of the protein, and not its secondary structure, that defines the genus of the claimed molecules. As Rost admits, "we are missing a variety of approaches relating secondary structure predictions explicitly to function" (page 214 right column). Therefore, the reference teaches away from Applicant's assertions that it is routine to predict protein function based on sequence information alone.

With regard to the instant claimed limitations, the structure of fragments of at least 15 amino acids of SEQ ID NO:2 or 4 cannot be readily envisioned by one of skill in the art based upon the guidance provided in the specification as-filed. The same argument applies to the hybridization language, because first, as noted supra, it reads on fragments, and second, requiring only moderate stringency, it allows for an extremely large number of variant sequences. Likewise, the 90% identity language allows for an extensive sequence variation, such that it is unpredictable, without undue experimentation, which of the numerous possible variants possess the functional properties of B7-4 molecules.

The scope of the claims must bear a reasonable correlation with the scope of enablement. See In re Fisher, 166 USPQ 18 24 (CCPA 1970). "It is not sufficient to define the recombinant molecule by its principal biological activity, e.g. having protein A activity, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property." Colbert v. Lofdahl, 21 USPQ2d, 1068, 1071 (BPAI 1992).

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Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended and newly added claims.

10. Rejection of claim 12 under 35 USC 102(b): The rejection of record has been withdrawn in view of Applicant's arguments.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 26 – 28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a New Matter rejection.*

Applicant's amendment asserts that no New Matter has been added and points to the specification at page 21, lines 14 – 17 for support for the newly added limitation of **claim 26** "50 – 60°C". However, the specification does not appear to provide an adequate written description of this temperature range, as it discloses a different range of 50 – 65°C.

The instant claims now recite limitations which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the

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specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the New Matter in the response to this Office Action.

Alternatively, Applicant is invited to clearly point out the written support for the instant limitations.

13. Conclusion: claims 13 – 15 appear to be allowable.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI

Patent Examiner

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March 14, 2005

Phillip Gambel

PHILLIP GAMBEL, PH.D
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3/17/05